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| APPLICATION NO.                                                                                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|-------------------------------------------------------------------------------------------------------|-------------|----------------------|-----------------------------|------------------------|
| 10/737,076                                                                                            | 12/16/2003  | Kyle S. Nelson       | 115.0010001                 | 5192                   |
| 7590<br>E. J. Brooks & Associates, PLLC<br>Suite 500<br>1221 Nicollet Avenue<br>Minneapolis, MN 55403 |             |                      | EXAMINER<br>WOODS, TERESA S |                        |
|                                                                                                       |             |                      | ART UNIT<br>3686            | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/737,076

**Applicant(s)**

NELSON ET AL.

**Examiner**

TERESA WOODS

**Art Unit**

3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the amendment filed 04/08/09. Claims 1, 12, 22, 30 and 36 have been amended. Claims 2-4 have been cancelled. Claims 1 and 5-38 remain pending.

### ***Specification Objections***

1. Claims 30-38 are objected, as based on a disclosure which is not enabling. A tabulation unit is critical or essential to the practice of the invention, but the Examiner was unable to locate it in applicant's Specification and is not enabled by the disclosure.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-21 are rejected under 35 U.S.C. 101 because no physical transformation is being produced. When a behavior routine is determined based on recorded sensor activations or counts, no specific algorithmic equations, formulas or program control values are used in a way where the data of any sensing threshold trend analysis could repeatedly produce results at the end of the proposed method steps.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 5, 8, 11 and 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over David (US 5,544,649 A) in view of Rogers (US 6,957,107 B2).

7. **Claim 1:**

David, as shown, discloses the following limitations:

- *monitoring a sensor activated by an individual* (See at least column 7; lines 37-42);
- *recording activation of the sensor* (see at least Fig. 10, column 10; lines 6-9);
- *determining a behavior routine of the individual based on recorded activations of the sensor* (See at least column 10; lines 13-17 and lines 62-66);
- *analyzing the recorded sensor activations to determine a behavior routine; and* (See at least Fig. 6, Fig. 7, column 20; lines 15-20)
- *in the behavior routine based on the analysis of the recorded sensor activations* (see at least column 20, lines 15-20).
- *Identifying a change in the behavior routine.*(See at least Fig. 6, column 20, lines 47-57). Here, routine surveillance serves as identifying patients behavior change.

Also, basic routine activities serve as behavior routines.

David does not disclose a computing device in communication with a sensor. However, Rogers discloses a computing device in communication with the sensor (See at least Fig. 4, column 3, lines 44-63). Here, the external monitor serves as a computing device in communication with a sensor. Also,

Rogers discloses with the computing device to determine a behavior routine (See at least column 3, lines 44-63, column 3, line 64 to column 4, line 20). In the second citation, Roger's computing device analyses multiple behavior routines.

David does not disclose a third party hierarchical selection based on changed behavior of patients. However, Rogers discloses initiating contact to a third party, on a hierarchical list of third party contacts in response to identifying the change in the behavior routine, wherein the third party on the hierarchical list to contact is selected based on a level of change in the behavior routine (See at least Fig. 2, Fig. 2A, Fig. 5, Fig. 10, column 16, lines 43-58, column 17, lines 1-25).

In the second citation, the hierarchy of contact serves as the hierarchical list to contact. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Davis's activity monitoring with the hierarchal computing device in communication with the sensors of Rogers for a comprehensive sensing method to better diagnose patients and notify the appropriate medical staff.

8. **Claim 5:**

David does not disclose the following limitation, but David discloses *further including initiating automated contact with a third party on a hierarchical list of third party contacts* (See at least Fig. 2, Fig. 2A, Fig. 5, Fig. 10, column 16,

lines 43-58, column 17, lines 1-25). In the second citation, the hierarchy of contact serves as the hierarchical list to contact. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Davis's activity monitoring with the hierarchal computing device in communication with the sensors of Rogers for a comprehensive sensing method to better diagnose patients and notify the appropriate medical staff.

9. **Claim 8:**

David, as shown, discloses the following limitations:

- *wherein the method further includes providing a sensor with a level of priority* (See at least column 8; lines 21-24). In the second citation, the general data and medical data gathered from sensors serve to divide the levels of priority.

10. **Claim 11:**

David discloses the limitations as shown in the rejections above. David does not disclose the following limitation, but Nichols discloses "*wherein using a pattern recognition algorithm includes using an algorithm based on a Bayesian decision theory* (See at least Fig. 21, Fig. 22, column 43, line 43 to column 44, line 48). Here, in Nichol's histogram diagnostic algorithm, the premature ventricular contractions caused increments are statistical inferences serve as a Bayesian decision property. Therefore, it would have been obvious to one of

ordinary skill in the art at the time of the invention to combine David's activity monitoring with a Bayesian decision theory algorithm of Rogers for a comprehensive sensing method to better diagnose any failed treatment or health of patients and to notify the appropriate medical staff.

**11. Claims 30-35:**

David discloses the limitations as shown below:

- *means for signaling that a sensor has been activated by an individual during activities of daily living* (See at least column 7; lines 37-40, 6; lines 21-25) ;

The first reference suggests the same daily activities being monitored by using sensors. The second reference describes a patient's daily activity and health having 24-hour supervision.

- *an analysis unit to analyze the tabulated signals to determine a behavior routine and identify changes in the behavior routine; and* (See at least column 49; lines 12-18).
- *a tabulation unit to tabulate the number of received signals* (See at least Fig. 7, Fig. 8, column 19, lines 24-29 and 45-47);

This reference describes the receiving unit that stores the transmitted sensor signals.



- *a contacting unit to initiate contact with a third party when the analysis unit identifies a change in the behavior routine* (See at least column 11; lines 9-14 and lines 61-65).

The first reference notifies the medical staff and the second reference notifies individuals helpful in the event of an emergency. David does not disclose the following limitation; however Nichols, as shown below, does

- *a receiver to receive signals*, (See at least Fig. 7, column 19; lines 25-33). This reference describes a device that receives sensor signals, but David does not disclose the following limitation. However, Rogers discloses *indicating that the sensor has been activated* (See at least column 14, lines 42-48).

David This reference embodies an analyzer and is more comprehensive to include images to see patient's behavior changes.

Referring to independent claim 30, David does not disclose a computing device in communication with a sensor. However, Rogers discloses *selected from a hierarchical list of third party contacts* when the analysis unit identifies a defined level change in the behavior routine (See at least Fig. 2, Fig. 10, column 16, lines 43-58, column 17, lines 1-13). Also, Rogers discloses *"indicating that the sensor has been activated"* (See at least column 14, lines 42-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Davis's activity monitoring sensor system with the hierarchal third party selection and activated hardware of Rogers for a

comprehensive sensing method to better diagnose patients and notify the appropriate medical staff.

12. **Claim 36:**

David, as shown, discloses the following limitations:

- *a receiver to receive activation signals from a sensor activated by an individual during activities of daily living* (See at least Fig. 7, column 5, lines 60-64, column 7, lines 36-40, column 19; lines 23-33, column 21; lines 26-29).

In the first two citations, David's monitoring system includes sensors and the measuring devices serves as receivers. In the last two citations and in figure 7, a receiver to receive signals from a patient's living activities are taught in David's monitoring system.

- *a processing unit to tabulate the received signals; and* (See at least Fig. 9, column 19; lines 25-28);
- *a contacting unit to initiate contact with a third party when directed by the processing unit* (See at least column 11; lines 61-65).

David does not disclose a computing device in communication with a sensor. However, Rogers discloses selected from a hierarchical list of third party contacts based on a defined level of change in a behavior routine when directed by the processing unit (See at least Fig. 2, Fig. 10, column 16, lines 43-58,

column 17, lines 1-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Davis's activity monitoring with the hierarchal third party selection when the behavior changes of Rogers for a comprehensive sensing method to better diagnose patients and notify the appropriate medical staff.

13. **Claim 37:**

David and Rogers do not disclose a self-operating computing device. However, David further discloses *wherein the device is a self contained, stand-alone device* (See at least Fig. 7, Fig. 10, column 18; lines 50-53).

14. **Claim 38:**

David discloses the limitations as shown in the rejections above. David does not disclose the following limitation, but Nichols discloses *"wherein the device includes an additional functionality selected from: a radio, a clock radio, an alarm clock, a telephone, and an answering machine"* (See at least column 8; lines 34-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine David's device for monitoring activity to Nichol's functionality selections to provide better options needed to review any failed monitoring and treatment during diagnosis.

15. Claims 6, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over David (US 5,544,649 A) in view of Rogers (US 6,957,107 B2) and in view of Nichols (US 5,330,513 A).

16. **Claim 6:**

David and Rogers disclose the limitations as shown in the rejections above. David and Rogers do not disclose the following limitation, but Nichols discloses *"further including grouping sensors within particular classes of daily activities"* (See at least Fig. 1, Fig. 2, column 5; lines 59-68, column 48, lines 17-20). In this reference, the sensors are grouped into two categories according to the rate control parameters. One measures the activity-based rate. The other measures the pressure-base rate. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine David's ability to monitor behavior sensors to Nichol's activity grouped sensors to provide optimum sensing to trouble-shoot patient problems.

17. **Claim 7:**

David and Rogers disclose the limitations as shown in the rejections above. David and Rogers do not disclose the following limitation, but Nichols

discloses *"wherein identifying a change in the at least one behavior includes comparing activations of a group of sensors within a class to a threshold"* (See at least Fig. 4, column 18; lines 1-2, column 26; lines 9-21). In this reference, the activity-base rate sensors, mentioned above in the limitations of claim 6, are further displayed as a range in sensor counts that signal adjustments once the threshold is overcome. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine David's ability to monitor behavior sensors to Nichol's behavior changed activation to provide optimum sensing to trouble-shoot patient problems.

18. **Claim 9:**

David and Rogers disclose the limitations as shown in the rejections above. David and Rogers do not disclose the following limitation, but Nichols discloses *"wherein identifying a change in the behavior routine includes weighting sensor activations differently based upon the sensor's level of priority"* (See at least column 48; lines 12-20). This reference embodies the distinction between sensors based on pre-set parameters. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine David's ability to monitor behavior sensors to Nichol's weighing sensors based on priority levels to better understand the details involved with the diagnosis of any failed treatment.

19. **Claim 10:**

David and Rogers disclose the limitations as shown in the rejections above. David and Rogers do not disclose the following limitation, but Nichols discloses *"wherein analyzing the recorded sensor activations to determine a behavior routine includes using a pattern recognition algorithm"* (See at least column 45; lines 19-35). This reference embodies the analyzing factors to determine a needed rate set with an algorithm. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine David's ability to monitor behavior sensors to Nichol's algorithm used to analyze behavior sensors to better understand the details involved with the diagnosis of any failed treatment.

20. Claims 12-21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols (US 5,330,513 A) in view of Rogers (US 6,957,107 B2).

Referring to independent claim 12, Nichols discloses when a statistical change exceeds a statistical threshold value and based on a level of statistical change (See at least Fig. 10-20, Abstract, column 4, lines 9-42). Here, all the rate control parameters and data parameter values serve as statistical changes with pre-determined thresholds.

Nichols does not disclose a computing device in communication with a sensor. However, Rogers discloses on a computing device in communication with the sensors (See at least Fig. 4, column 3, lines 44-63) and the computing device (See at least column 3, line 64 to column 4, line 20). Also, Rogers discloses wherein the third party on the hierarchical list to contact is selected (See at least Fig. 2, Fig. 10, column 16, lines 43-58, column 17, lines 1-13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Nichols's exceeded statistical threshold feature with the hierarchal computing device in communication with the sensors of Rogers for a comprehensive sensing method to better trouble-shoot and diagnose patient's problems.

21. Claims 22-29 is rejected under 35 U.S.C. 103(a) as being unpatentable over David (US 5,544,649 A) in view of Nichols (US 5,330,513 A) further in view of Rogers (US 6,957,107 B2).

Referring to independent claim 22, David discloses the limitations as shown below:

- *sensing data counts associated with an activity of daily living for an individual* (See at least column 6; lines 21-25, column 22; lines 20-23) ;

David does not disclose a computing device in communication with a sensor. However, Nichols discloses and a level of statistical change in the data counts (See at least Fig. 10-20, Abstract, column 4, lines 9-42). Here, all the rate control parameters and data parameter values serve as having statistical changes with pre-determined thresholds, based on sensor counted events.

Nichols, also discloses:

- *determining a statistical change in the data counts relative to expected data counts for the activity of daily living* (See at least Fig. 2A, column 5; lines 59-63);
- *when the statistical based change exceeds the statistical threshold value* (See at least column 22, line 65 to column 23, line 15).
- *identifying when the statistical change in the data counts relative expected data counts exceed a statistical threshold value* (See at least Fig. 2A, column 5; line 65 to column 23, line 15);
- *based on the activity of daily living for which the statistical change in the data counts relative expected data counts exceed the statistical threshold value; and* (See at least Fig. 2A, column 22; line 65 to column 23; line 15);

When referring to Fig. 2A, emphases are put on a sensor target rate versus the actual counts of an individual's physical activity. The second reference explains a sensor's count performance falling above the expected optimization range.



- and a level of statistical change in the data counts (See at least Fig. 10-20, Abstract, column 4, lines 9-42). Here, all the rate control parameters and data parameter values serve as having statistical changes with pre-determined thresholds, based on sensor counted events.

Neither references disclose the following limitations. However, Rogers discloses, *selecting a third party on a hierarchical third party list* and *"initiating automated contact to the third party on the hierarchical third party list* (See at least Fig. 2, Fig. 2A, Fig. 5, Fig. 10, column 16, lines 43-58, column 17, lines 1-25).

In the second citation, the hierarchy of contact serves as the hierarchical list to contact. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine David and Nichols activity monitoring with the hierarchal computing device in communication with the sensors of Rogers for a comprehensive sensing method to better diagnose patients and notify the appropriate medical staff.

***Response to Arguments***

22. Applicant' arguments with respect to claims 6, 7, 9 and 10, 12-21 have been fully considered but are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed 04/08/09.
23. (1) Applicant argues on the basis that the David reference does not teach a receiver. Rather, David's receiver unit works with a memory unit and signal transmitter.
24. (2) Applicant argues on the basis that the David reference does not teach a third party contact on a hierarchal list. Rather, Rogers includes a hierarchy of medical personnel contacts for emergency, non-emergency, threatening and non-threatening patient conditions.
25. (3) Applicant argues on the basis that the Nichols reference does not teach or suggest monitoring a sensor activated by an individual, but the monitoring devices of both Nichols and David are activated by individuals wearing the device. Another is within the basis of recording activation of the sensor on a computing device, but Nichol's data storage device is based on sensor pace rate control. Another argument is within the basis of determining a behavior routine of the individual based on recorded activations of the sensor, but Nichol's data storage device was based on patient physiological rate changes which is a relevant term of Nichol's invention. Another is within the basis of analyzing the recorded sensor activations with the computing device to determine a behavior

routine. However, David's data analysis and measurement of medical parameters are used to determine a behavior. Another argument is within the basis of identifying a change in the behavior routine based on the analysis of the recorded sensor activations, but both David and Nichols have resulting data and measured parameter values stemming from patient sensor activity.

***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA WOODS whose telephone number is (571) 270-5509. The examiner can normally be reached on Mon-Fri, 7:30am - 5:00 pm, east.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

Teresa Woods, Art Unit 3686

09/03/09

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
Group Art Unit 3686